

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

VICKI STINNETTE, GENIE BRAZZEAL,
CARRIE PACK, AUSTIN PACK,
SAMUEL EISMONT, and ANGELA
MILLER,

Plaintiffs,

V.

MEDTRONIC, INC., MEDTRONIC
MINIMED, INC., and MEDTRONIC
PUERTO RICO OPERATIONS COMPANY,

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs Vicki Stinnette, Genie Brazzeal, Carrie Pack, Austin Pack, Samuel Eismont, and Angela Miller complain of Defendants Medtronic, Inc., Medtronic MiniMed, Inc., and Medtronic Puerto Rico Operations Company, as follows.

I. Parties

1. Plaintiff Vicki Stinnette is, and at all times material hereto was, an individual residing in Hockley, Texas, and is a citizen of Texas.

2. Plaintiff Genie Brazzeal, is, and at all times material hereto was, an individual residing in Savannah, Georgia, and is a citizen of Georgia.

3. Plaintiff Carrie Pack is a permanent resident of Texas who is temporarily residing in North Carolina as a result of her husband's service with the United States Army; she is a citizen of Texas. Plaintiff Austin Pack, Carrie Pack's husband, is also a resident and citizen of Texas.

4. Plaintiff Samuel Eismont is, and at all times material hereto was, an individual residing in Gladstone, Missouri, and is a citizen of Missouri.

5. Plaintiff Angela Miller is, and at all times material hereto was, an individual residing in Deep Gap, North Carolina, and is a citizen of North Carolina.

6. Defendant Medtronic, Inc. ("Medtronic") is a corporation organized under the laws of Minnesota, with its principal place of business in Minnesota. Medtronic routinely conducts business in Texas and is registered to conduct business in Texas. It may be served with process by either serving its registered agent, CT Corporation System, 350 North St. Paul Street, Dallas, Texas, 75201-4240 or its President, Jean-Luc Butel, at 710 Medtronic Pkwy, Minneapolis, MN 55432-5603.

7. Defendant Medtronic MiniMed, Inc. ("Medtronic MiniMed") is a corporation organized under the laws of Delaware, with its principal place of business in California. It is not registered to do business in Texas and may be served by serving its registered agent for service of process, CT Corporation System, at 818 W 7th St., Los Angeles, California 90017-3407.

8. Defendant Medtronic Puerto Rico Operations Company ("Medtronic PR Operations Co.") is a corporation organized under the laws of Cayman Islands, with its principal place of business in Puerto Rico. Since the Cayman Islands is an overseas territory of Great Britain, Plaintiffs may serve Medtronic PR Operations Co. through the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters.

9. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. shall be collectively referenced as "Defendant," "Defendants," or "Medtronic."

II. Jurisdiction and Venue

10. This Court possesses diversity jurisdiction under 28 U.S.C. § 1332(a) because the matter in controversy: (a) exceeds the sum or value of \$75,000.00, exclusive of interest and costs and (b) is between citizens of different states.

11. Medtronic is subject to the Court's personal jurisdiction because Medtronic has sufficient minimum contacts with Texas such that the exercise of jurisdiction over Medtronic would not offend traditional notions of fair play and substantial justice. The Court has general jurisdiction over Medtronic because it maintains corporate offices in Fort Worth, Texas and San Antonio, Texas. The Court has specific jurisdiction over the claims of Plaintiffs Vickie Stinnette, Carrie Pack and Austin Pack against Medtronic because Medtronic marketed and distributed the medical equipment giving rise to such Plaintiffs' claims in Texas, and Plaintiffs Vicki Stinnette and Carrie Pack were each prescribed and began using that medical equipment in Texas.

12. Medtronic MiniMed is subject to the Court's personal jurisdiction because Medtronic MiniMed has sufficient minimum contacts with Texas such that the exercise of jurisdiction over Medtronic MiniMed would not offend traditional notions of fair play and substantial justice. The Court has specific jurisdiction over the claims of Plaintiffs Vickie Stinnette, Carrie Pack and Austin Pack against Medtronic because Medtronic marketed and distributed the medical equipment giving rise to such Plaintiffs' claims in Texas, and Plaintiffs Vicki Stinnette and Carrie Pack were each prescribed and began using that medical equipment in Texas.

13. Medtronic PR Operations Co. is subject to the Court's personal jurisdiction because Medtronic PR Operations Co. has sufficient minimum contacts with Texas such that the exercise of jurisdiction over Medtronic PR Operations Co. would not offend traditional notions of fair play and substantial justice. The Court has specific jurisdiction over the claims of Plaintiffs Vickie Stinnette,

Carrie Pack and Austin Pack against Medtronic because Medtronic marketed and distributed the medical equipment giving rise to such Plaintiffs' claims in Texas, and Plaintiffs Vicki Stinnette and Carrie Pack were each prescribed and began using that medical equipment in Texas.

14. Venue is appropriate in this court because all Defendants are subject to jurisdiction in this district at the time of the commencement of this lawsuit. 28 U.S.C. § 1391(c).

III. Statement of Facts Applicable to All Counts

A. Medtronic Insulin Pump

15. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. manufactured, marketed and distributed the "MiniMed" insulin pump which was advertised to provide for the regular introduction of a measured amount of insulin into a diabetic user's system. To receive insulin from a MiniMed insulin pump, a patient is required to use a "Paradigm Quick-Set infusion set," also manufactured, marketed and distributed by Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co., which consists of disposable plastic tubes which transport the insulin from the pump to the patient's body.

16. Plaintiffs had no way of knowing, however, that the Paradigm Quick-Set infusion sets that they were required to use were defective in design, manufacture, and marketing, and that, even when used in conformance with Medtronic's instructions, the sets were prone to deliver incorrect and life-threatening doses of insulin.

B. Medtronic: High Ideals, Low Quality

1. What Medtronic Claims To Do

17. Medtronic touts its leadership in the medical device industry: "No other company has 25 years of continuous leadership in diabetes device solutions that improve patients' lives. At Medtronic Diabetes, we are passionate about diabetes care, have a highly trusted brand and a proven

track record for advancing solutions." This claim is echoed in part of Medtronic's mission statement in which Medtronic vows to "strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service."

2. What Medtronic Actually Does

a. The FDA's June 1, 2009 Letter To Medtronic

18. In sharp contrast to these virtuous ideals are statements from a June 1, 2009 letter from the United States Food and Drug Administration to William A. Hawkins, Medtronic's president and chief executive officer regarding Medtronic PR Operations Co., the firm where MiniMed Paradigm Insulin Pumps are manufactured. In criticizing Medtronic's manufacturing and reporting processes, the FDA cited Medtronic for:

Failure to report to FDA no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur...

19. In contravention of applicable regulations, Medtronic had failed to report an incident involving a MiniMed Paradigm insulin pump in which "device failure or malfunction may have contributed to or caused the user's hospitalization and the device's malfunction would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."

20. The FDA also found fault with the personnel that Medtronic entrusted at its manufacturing facility in Puerto Rico with determining whether a Medtronic device was dangerous. Specifically, the FDA cited Medtronic for:

Failure to have a person who is qualified to make a medical judgment reasonably conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it

were to recur, as required by [United States Federal Law]. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers, under [United States Federal Law].

21. As the FDA's investigation revealed, Medtronic's employee entrusted with making this critical determination "only had a high school diploma with some additional in-house training."

22. In listing these and other violations, the FDA concluded that the problems may be "symptomatic of serious problems in" Medtronic's manufacturing procedures and its quality controls.

23. None of the cited violations reflect Medtronic's hollow promise to strive "without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service."

b. The Paradigm Quick-Set Recall

24. On June 29, 2009, the FDA issued a "Class 1" recall of many of Medtronic's insulin infusion sets labeled as "Paradigm Quick-Set Infusion Sets." Specifically, the FDA recalled infusion sets with model numbers MMT-396, MMT-397, MMT-398, and MMT-399. The devices had been manufactured and distributed from December 1, 2007 through June 18, 2009. A Class 1 recall is "the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious injury or death." As the FDA noted, "These infusion sets may not allow the insulin pump to vent air pressure properly. This could potentially result in the device delivering too much or too little insulin and may cause serious injury or death." In the recall, Medtronic recalled three million of the disposable infusion sets.

C. Plaintiffs are Diabetic

25. Plaintiffs have all been diagnosed as being diabetic and are required to infuse insulin into their body to control their blood sugar.

26. Insulin is a hormone that is required to sustain life. In most people, insulin is naturally produced in the pancreas. A person with diabetes, however, either does not produce insulin in sufficient amounts or does not produce insulin at all.

27. The Paradigm Quick-Set infusion sets used by Plaintiffs included sets with model numbers MMT-396, MMT-397, MMT-398, and MMT-399.

1. Vicki Stinnette

28. In April 2007, Plaintiff Vicki Stinnette's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

29. Plaintiff Vicki Stinnette was correctly using the MiniMed insulin pump with a Medtronic Paradigm Quick-Set infusion set when, on November 7, 2008, she failed to receive the correct does of insulin to manage her diabetic condition. Consequently, Plaintiff Vicki Stinnette was hospitalized for diabetic ketoacidosis.

30. As a direct and proximate result of the acts and omissions of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co., Plaintiff has suffered and will continue to suffer damages as are more fully set out below.

2. Genie Brazzeal

31. Plaintiff Genie Brazzeal's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set Infusion Set.

32. Plaintiff Genie Brazzeal was correctly using the MiniMed insulin pump with a Medtronic Paradigm Quick-Set infusion set when, on July 15, 2009, she failed to receive the correct does of insulin to manage her diabetic condition. Consequently, Plaintiff Genie Brazzeal was hospitalized due to the failure of the pump.

33. As a direct and proximate result of the acts and omissions of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co., Plaintiff has suffered and will continue to suffer damages as are more fully set out below.

3. Carrie Pack

34. In 1999, Plaintiff Carrie Pack's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set infusion set.

35. Carrie Pack was correctly using a Medtronic MiniMed insulin pump with a Medtronic Paradigm Quick-Set infusion set when, on March 12, 2009 and on March 20, 2009, she failed to receive the correct dose of insulin to manage her diabetic condition. Carrie Pack suffered a near-fatal diabetic crisis which resulted in her hospitalization.

36. As a direct and proximate result of the acts and omissions of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co., Plaintiffs Carrie Pack and Austin Pack have suffered and will continue to suffer damages as are more fully set out below.

4. Samuel Eismont

37. Plaintiff Samuel Eismont's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set infusion set.

38. Samuel Eismont was correctly using the MiniMed insulin pump with a Medtronic Paradigm Quick-Set infusion set when, in October 2007, he failed to receive the correct dose of insulin to manage his diabetic condition. Consequently, Samuel Eismont was hospitalized in October 2007 and has since been hospitalized twelve (12) times due to the failure of the pump.

39. As a direct and proximate result of the acts and omissions of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co., Plaintiff Samuel Eismont has suffered and will continue to suffer damages as are more fully set out below.

5. Angela Miller

40. Plaintiff Angela Miller's doctor prescribed the use of the MiniMed insulin pump, with the Paradigm Quick-Set infusion set.

41. Angela Miller was correctly using the MiniMed insulin pump with a Medtronic Paradigm Quick-Set infusion set when, on June 2, 2009, she failed to receive the correct dose of insulin to manage her diabetic condition. Consequently, Angela Miller was hospitalized due to the failure of the pump.

42. As a direct and proximate result of the acts and omissions of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co., Plaintiff Angela Miller has suffered and will continue to suffer damages as are more fully set out below.

IV. Causes of Action

A. Count One: Strict Liability

43. Plaintiffs adopt by reference each and every paragraph of the Statements of Facts Applicable to All Counts of the Complaint as if fully copied and set forth at length herein.

44. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. were the designers, manufacturers, marketers, sellers and/or distributors of various medical instrumentalities, including the MiniMed insulin pump and its component parts, including the Medtronic Paradigm Quick-Set infusion sets, for use by ultimate consumers, including each Plaintiff, requiring insulin to control their diabetic condition.

45. Plaintiffs each purchased the medical instrumentalities and the component parts manufactured by Medtronic, Medtronic MiniMed and/or Medtronic PR Operations Co. from distributors of diabetic supplies as well as directly from Medtronic, Medtronic MiniMed and/or Medtronic PR Operations Co. The component parts were in their original packaging which was

firmly sealed and in the condition existing at the time of their delivery by Medtronic, Medtronic MiniMed and/or Medtronic PR Operations Co. to its distributors and/or to each Plaintiff's physicians or other health care providers or to Plaintiff individually.

46. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. designed, manufactured, marketed, sold, and/or distributed the medical instrumentalities and the component parts thereof used by each Plaintiff in the treatment of her diabetic condition.

47. The medical instrumentalities including the MiniMed insulin pump and its component parts, including the Medtronic Paradigm Quick-Set infusion sets, reached Plaintiffs without substantial change in condition from when they left Medtronic's, Medtronic MiniMed's and Medtronic PR Operations Co.'s control.

48. The MiniMed insulin pump together with its component parts, including the Medtronic Paradigm Quick-Set infusion sets, was defective and unreasonably dangerous in that it failed to properly infuse the required dosage of insulin into each Plaintiff's system.

49. The faulty design marketing and/or manufacture of the component parts of the devices manufactured, produced and placed into the stream of commerce by Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. were a producing cause of in the injuries and damages to Plaintiffs as set out herein.

1. Marketing Defect (Failure To Warn)

50. The risk that an incorrect dosage of insulin might be delivered was a risk of harm that was inherent in the product, or that might arise from the intended or reasonably anticipated use of the product.

51. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. either actually knew, or reasonably should have foreseen, the aforesaid risk of harm at the time it marketed the product.

52. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. failed to warn, or to adequately warn, of the aforesaid danger, or failed to give instructions, or adequate instructions, on how to avoid the danger.

53. The product was unreasonably dangerous as marketed because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer with the knowledge common to the community as to its characteristics.

2. Design Defect

54. The design of the product rendered it unreasonably dangerous, taking into consideration the utility of the product and the risk involved in its use.

55. There was a safer alternative design other than the one used that in reasonable probability:

- (a) would have prevented or significantly reduced the risk of incorrect doses of insulin being administered and causing personal physical injury or physical sickness that would not have impaired the products utility; and
- (b) that was economically and technologically feasible at the time the product left Medtronic's, Medtronic MiniMed's and Medtronic PR Operations Co.'s control by the application of existing or reasonably achievable scientific knowledge.

3. Manufacturing Defect

56. The product deviated, in its construction or quality, from its specifications or planned output in a manner that rendered it unreasonably dangerous.

57. The product was unreasonably dangerous as manufactured because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer with the knowledge common to the community as to its characteristics.

58. The foregoing defects, more particularly described above, were a producing cause of each Plaintiff's injuries and damages, more particularly described below.

B. Count Two: Breach Of Express Warranty As Applicable To Medtronic And Medtronic Minimed

59. Plaintiffs adopt by reference each and every paragraph of the statement of Facts Applicable to All counts of this Complaint as if fully copied and set forth at length herein.

60. At all times material hereto Medtronic and Medtronic MiniMed expressly represented and warranted to both healthcare providers and to the ultimate consumers of its products, including each Plaintiff, that the MiniMed insulin pump including its component parts, the Medtronic Paradigm Quick-Set infusion sets, would safely and efficiently deliver the required measured dose of insulin into the consumers' system to prevent blood sugar imbalance and the consequences thereof.

61. Prior to the purchase of the medical instrumentalities and the component parts thereof by Plaintiffs as alleged above, Medtronic and Medtronic Minimed induced Plaintiffs' purchase of said instrumentalities by expressly warranting or representing directly to Plaintiff, as well as to their physician and/or other health care providers, that the instrumentalities and the component parts thereof would safely and efficiently deliver the required dosage of insulin at the specific times required.

62. In purchasing the instrumentalities and their component parts, Plaintiffs relied on the skill and judgment of Medtronic and Medtronic MiniMed and on Medtronic's and Medtronic MiniMed's express warranties and representations as described above. Such warranties and

representations formed a part of the basis of the bargain in which Plaintiffs selected and purchased the MiniMed Pump and its component parts, including the Quickset infusing sets.

63. Medtronic and Medtronic MiniMed breached the express warranty by designing, manufacturing and marketing a defective product that, in fact, failed to deliver the prescribed measured dosage of insulin at the specific time required.

64. Medtronic's and Medtronic MiniMed's breach of express warranties proximately and directly caused Plaintiffs' injuries and damages as set out herein.

C. Count Three: Breach Of Implied Warranty Of Fitness For A Particular Purpose

65. Plaintiffs adopt by reference each and every paragraph of the statement of Facts Applicable to All Counts of this Complaint as if fully copied and set forth at length.

66. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. knew or should have known the particular purpose for which Plaintiffs purchased the medical instrumentality and its component parts because the purpose for which Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. sold these particular medical devices was solely for the infusion of insulin into the ultimate consumers' system to control his or her diabetic condition.

67. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. impliedly warranted that the MiniMed insulin pump and its component parts including the Medtronic Paradigm Quick-Set infusion sets were fit for the purpose for which they were designed and manufactured and that they were, in fact, suitable for the use made by each Plaintiff.

68. In purchasing and using the medical devices described herein, Plaintiffs relied on Medtronic's, Medtronic MiniMed's and Medtronic PR Operations Co.'s skill and judgment and the

implied warranty of fitness for a particular purpose for which Plaintiffs purchased the insulin pump and its component parts.

69. The MiniMed insulin pump and its component parts, including the Medtronic Paradigm Quick-Set infusion sets, were not fit for use for its intended purpose because, either separately or in conjunction, they had a tendency to cause the infusion of an incorrect dose of insulin into the system of each Plaintiff.

70. Medtronic's, Medtronic MiniMed's and Medtronic PR Operations Co.'s breach of the implied warranty of fitness for a particular purpose directly and proximately caused Plaintiffs' injuries and damages more fully set out below.

D. Count Four: Breach Of Implied Warranty Of Merchantability As Applicable To Medtronic And Medtronic Minimed

71. Plaintiffs adopt by reference each and every paragraph of the statement of Facts Applicable to All Counts of this Complaint as if fully copied and set forth at length.

72. Medtronic and Medtronic MiniMed impliedly warranted that the medical instrumentalities and the component parts thereof were of a merchantable quality, fit, safe and in proper condition for the ordinary use for which such devices are designed, manufactured, marketed and used.

73. In purchasing and using the instrumentalities designed, produced and marketed by Medtronic and Medtronic MiniMed, the Plaintiffs relied on Medtronic's and Medtronic MiniMed's skill and judgment, and the implied warranty of merchantability for the purpose for which Plaintiffs purchased said instrumentalities.

74. The medical devices and instrumentalities and the component parts thereof purchased by Plaintiffs were not merchantable in that among other things, either in conjunction or separately,

they had the tendency to fail to introduce the required regular measured dosage of insulin into each Plaintiff's body. For this reason, the product was unfit for ordinary purposes. The product was unfit for ordinary purposes because it was unreasonably dangerous.

75. Medtronic's and Medtronic MiniMed's breach of the implied warranty of merchantability as is particularly set forth herein directly and proximately resulted in Plaintiffs' injuries and damages as set out below.

E. Count Five: Negligence

76. Plaintiffs adopt by reference each and every paragraph of the statement of Facts Applicable to All Counts of this Complaint as if fully copied and set forth at length.

77. At all times material hereto Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. were engaged in the manufacture of medical devices and instrumentalities used to infuse measured doses of insulin into the systems of patients with diabetic conditions. These devices and instrumentalities were marketed and sold to various physicians and other health care providers and directly to the ultimate consumers, including each Plaintiff.

78. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. owed to Plaintiffs and the public a duty to use reasonable care in the testing and inspecting of their medical instrumentalities and devices, in designing the devices and the component parts thereof and in manufacturing and marketing those medical devices and instrumentalities and the component parts thereof, including the MiniMed insulin pump and the Medtronic Paradigm Quick-Set infusion sets.

79. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. were negligent in their design, manufacture, and marketing of the MiniMed insulin pump and its component parts including the Medtronic Paradigm Quick-Set infusion sets in one or more of the following particulars, among others:

- (a) In designing the insulin pump and its component parts, including the Medtronic Paradigm Quick-Set infusion sets, in a manner which caused them to fail to vent properly resulting in an incorrect dosage of insulin into the system of patients including Plaintiff.
- (b) In failing to adequately test the MiniMed insulin pump and its component parts including the Medtronic Paradigm Quick-Set infusion sets.
- (c) In failing to properly market the MiniMed insulin pump and its component parts including the Medtronic Paradigm Quick-Set infusion sets.
- (d) In failing to provide adequate warnings, information or both of the risks and hazards of the medical device and its component parts.

80. The design, manufacture, marketing, and function of the MiniMed insulin pump with its component parts including the Medtronic Paradigm Quick-Set infusion sets were within the exclusive control of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co.

81. The specific facts concerning the design, manufacture, marketing, and function of the MiniMed insulin pump and its component parts including the Medtronic Paradigm Quick-Set infusion sets are particularly within the knowledge of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. and the Plaintiffs have no means of ascertaining the method or manner in which the pump and its component parts were designed, manufactured or marketed.

82. The medical instrumentalities designed, produced and marketed by Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. came into each Plaintiff's possession in the same condition as they were in when they left the control of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co.

83. The occurrences causing harm to Plaintiffs, as described above, were ones which in the ordinary course of events would not have occurred without negligence on the parts of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. For these reasons, the doctrine of *res ipsa loquitur* permits a finder of fact to infer negligence on the part of defendants.

84. As a direct and proximate result of the acts and omissions of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co., whether taken singularly or in any combination, the Plaintiffs suffered injuries and damages as more fully set forth below.

V. Punitive Damages

85. Plaintiffs adopt by reference each and every foregoing paragraph as if fully copied and set forth at length herein.

86. The conduct of Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co., when viewed objectively from Medtronic's, Medtronic MiniMed's and/or Medtronic PR Operations Co.'s standpoints at the time of its occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to diabetics, including Plaintiffs.

87. Further, Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. had actual, subjective awareness of the risk involved with respect to their conduct, but nevertheless proceeded with conscious indifference to the rights, safety and welfare of others. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. knew that there was a high probability that inaccurate doses of insulin could occur and would result in serious injury.

88. Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. are liable for punitive damages in respondeat superior for the conduct of their agents, representatives or employees that engaged in the above conduct to one or more of the following reasons:

- (a) Medtronic, Medtronic MiniMed and/or Medtronic PR Operations Co. authorized the doing and manner of such conduct;
- (b) one or more of such agents, representatives or employees were unfit, and Medtronic, Medtronic MiniMed and/or Medtronic PR Operations Co. were reckless in employing him or her;
- (c) one or more of such agents, representatives or employees were employed by Medtronic, Medtronic MiniMed and/or Medtronic PR Operations Co. in a

managerial capacity and acting within the scope of such and acting within the scope of such agency or employment;

- (d) Medtronic, Medtronic MiniMed and/or Medtronic PR Operations Co. or a manager of Medtronic, Medtronic MiniMed and/or Medtronic PR Operations Co. ratified or approved the conduct of such agents, representatives or employees.

VI. Damages Applicable to All Counts

89. Plaintiffs adopt by reference each and every foregoing paragraph as if fully copied and set forth at length herein.

90. As a producing and proximate result of Medtronic's product and Medtronic's conduct as described above, Plaintiffs suffered in the past, and in reasonable medical probability will continue to suffer in the future the following injuries and damages:

- (a) physical pain, past and future;
- (b) mental anguish, past and future;
- (c) physical impairment, past and future;
- (d) reasonable and necessary medical expenses, past and future;
- (e) loss of earnings, earnings capacity, or both, past and future;
- (f) loss of the enjoyment of life, past and future; and,
- (g) other incidental damage(s).

91. As a producing and proximate result of the defective product and Medtronic's wrongful conduct, each spousal Plaintiff suffered in the past, and in reasonable medical probability will continue to suffer in the future, the following injuries and damages, among others:

- (a) loss of consortium, past and future; and
- (b) loss of household services, past and future.

VII. Jury Demand

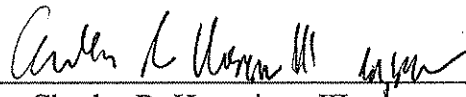
92. Plaintiffs hereby request a trial by jury.

VIII. Prayer

WHEREFORE Plaintiffs pray that Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. be cited to appear and answer herein and that, upon final trial, Plaintiffs be awarded judgment against Medtronic, Medtronic MiniMed, and Medtronic PR Operations Co. jointly and severally:

- (a) for compensatory damages, jointly and severally, in excess of the minimum jurisdictional limits of this Court;
- (b) for punitive damages, severally, in excess of the minimum jurisdictional limits of this Court;
- (c) prejudgment interest;
- (d) post-judgment interest;
- (e) costs of Court; and
- (f) such other and further relief to which Plaintiffs show themselves justly entitled to receive.

Respectfully submitted,



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